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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re United States Patent Application of: Docket No .: 4179-126 Applicants: SHAR, TILAK M. Comf. No.: 2458 Application No.: 10/633,238 Art Unit: 3728 David T. Fidei Date Filed: August 1, 2003 Examiner: PRESS-FLAT CENTRIFUGE Customer No.: Title:

TUBE AND SPECIMEN

COLLECTION ASSEMBLY COMPRISING SAME

23448

DECLARATION OF TILAK M. SHAH UNDER 37 C.F.R. § 1.131 IN U.S. PATENT APPLICATION NO. 10/633,238

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

I, Tilak M. Shah, hereby declare:

THAT I am the inventor of the subject matter claimed in United States Patent Application No. 1. 10/633,238 filed August 1, 2003 in the United States Patent and Trademark Office and entitled "PRESS-FLAT CENTRIPUGE TUBE AND SPECIMEN COLLECTION ASSEMBLY COMPRISING SAME," hereafter referred to as the "Application."

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- 2. THAT the Application as originally filed broadly discloses centrifuge tubes having integral hinge elements at opposing sides of the body to facilitate compression flattening of at least a portion of the body, and that the Application broadly claims such devices in the following independent claims 22 and 31:
 - 22. A centrifuge tube having a body with a closed distal end, an open proximal end, and integral hinge elements at opposing sides of the body to facilitate compression flattening of at least a portion of the body, wherein the body has a substantially uniform diameter along the open proximal end
 - 31. A centrifuge tube having a body with a closed distal end, an open proximal end, and integral hinge elements at opposing sides of the body to facilitate compression flattening of at least a portion of the body, wherein the body has a central axis extending through the closed distal end and the open proximal end, the body has an average cross-sectional area in a direction perpendicular to the central axis, and the open proximal end has a cross-sectional area at least as large as the average cross-sectional area.
- 3. THAT I have become aware of the existence of U.S. Patent Publication Number 2004/0267181 in the names of James J. Tuite and Peter Andreotti, assigned to "ASD" of Fort Lauderdale, Florida, entitled "SWAB SAMPLE COLLECTION AND RECOVERY DEVICE," and disclosing a centrifuge tube having "a spine (6) along the side wall which allows for compression of the tube at the compressible indent (7) shown in FIG. 2b" (See Publication, ¶ [0033] & Figs. 2a-2b), with such patent publication claiming benefit of U.S. Provisional Patent Application No. 60/482,517;
- THAT I have been informed by my legal representatives that any potential rejection of the claims of the Application based on U.S. Patent Publication Number 2004/0267181 can be

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overcome by presenting evidence to the United States Patent and Trademark Office of my possession of the claimed invention prior to the effective date of U.S. Patent Publication Number 2004/0267181, and that such effective date has been identified to me by such legal representatives as the date when U.S. Provisional Patent Application No. 60/482,517 was filed on June 26, 2003 (such date hereafter being referred to as the "Effective Date").

- 5. THAT my company, Polyzen Inc., was hired prior to the Effective Date by ASD of Fort Lauderdale, Florida to develop a prototype centrifuge tube, and that I personally conceived, prior to the Effective Date and without any suggestion from James Tuite, individuals at ASD, or others, a centrifuge tube having integral hinge elements at opposing sides of the body to facilitate compression flattening of at least a portion of the body;
- 6. THAT attached as Exhibit 1 hereof is a true and exact copy of a facsimile cover page and drawing evidencing development by me of a centrifuge tube having integral hinge elements at opposing sides of the body to facilitate compression flattening of at least a portion of the body, on which all dates have been blacked out, but which dates are prior to the Effective Date as listed hereinabove; that such facsimile cover page and drawing were sent as indicated on the cover page to "James Tuite" of ASD at facsimile number "434-656-9282" prior to the Effective Date with the following notation in my own handwriting:

"Review DWG. Please Review and approve. Initial it and fax back to us. Thanks, Tilak"; that the drawing page (labeled in the title block as "VIALS") clearly depicts a contribuge tube having integral hinge elements at opposing sides of the body; and that the drawing page labels such hinge elements as "Spine to allow flexing, to wipe swab;"

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7. THAT such disclosure about forming a centrifuge tube having integral hinge cluments at opposing sides of the body evidences my conception of the inventive subject matter claimed in claims 22 and 31 of the Application, which relate to centrifuge tubes having integral hinge elements at opposing sides of the body to facilitate compression flattening of at least a portion of the body.

As a below-named declarant, I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements, and the like, so made are punishable by fine or imprisonment, or both, under Section 1001 or Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

EXHIBIT 1